IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

TRUTEK CORP., *Plaintiff/Counter-Defendant*, v. BLUEWILLOW BIOLOGICS, INC. *Defendant/Counter-Plaintiff*, ROBIN ROE 1 through 10 (fictitious names); ABC CORPORATION 1 through 10 (fictitious names), *Defendants*.	Case No. 2:21-cv-10312 Hon. Stephen J. Murphy, III Mag. R. Steven Whalen

DEFENDANT BLUEWILLOW BIOLOGICS, INC.'S
OPENING CLAIM CONSTRUCTION BRIEF

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Pursuant to the Order Setting Claim Construction (Dkt. 35), BlueWillow Biologics, Inc. ("BlueWillow") submits its Opening Claim Construction Brief.

I. LEGAL STANDARD

A. Claim Construction Generally

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). As this district has explained,

> Claims of a patent are short and concise statements, expressed with great formality, of the metes and bounds of the patented invention. Each claim is written in the form of a single sentence. Claim construction is the manner in which courts determine the meaning of the terms in the claim. "The construction of claims is simply a way of elaborating the normally terse claim language: ***in order to understand and explain, but not to change, the scope of the claims***."

Recticel Automobilesysteme GmbH v. Auto. Components Holdings, LLC, No. 2:10-cv-14097, 2012 WL 1276003, at *2 (E.D. Mich. Apr. 16, 2012) (quoting *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1580 (Fed. Cir. 1991)) (emphasis added).

Claim construction is an issue of law for the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–79 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). "[T]he claim construction inquiry . . . begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158

F.3d 1243, 1248 (Fed. Cir. 1998). Words of a claim generally are given "their ordinary and customary meaning" as understood by one of "ordinary skill in the art at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (*en banc*).

In construing a claim, the court must first consider the intrinsic evidence, consisting of the claim language, the patent specification, and the prosecution history. *Id.* at 1313. "The appropriate starting point . . . is always with the language of the asserted claim itself." *Comark Commc'n, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). The specification is also highly instructive and is the "single best guide to the meaning of a disputed term[.]" *Phillips*, 415 F.3d at 1312.

A court may also consider extrinsic evidence, "which consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Id.* at 1317 (internal quotation omitted). "However, while extrinsic evidence can shed useful light on the relevant art, . . . it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Id.*

B. Indefiniteness

During claim construction, the court may also find claims invalid as indefinite. Indefiniteness is a question of law "inextricably intertwined with claim construction." *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1379 (Fed. Cir. 1999). And, as a result, it is proper—often necessary—to consider indefiniteness at the claim construction stage. *See Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008) ("Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction."); *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001) ("[D]etermination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims."), *abrogated on other grounds* by *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 912 n.9 (2014).

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 572 U.S. at 901. The burden of establishing invalidity based on indefiniteness rests on the party asserting invalidity and must be proven by clear and convincing evidence. *See Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*,

743 F.3d 1359, 1366 (Fed. Cir. 2014). *Nautilus* explained: "[f]irst, definiteness is to be evaluated from the perspective of someone skilled in the relevant art . . . . Second, in assessing definiteness, claims are to be read in light of the patent's specification and prosecution history . . . . Third, definiteness is measured from the viewpoint of a person skilled in the art at the time the patent was filed." 572 U.S. at 908 (internal quotations removed) (emphasis removed).

II. OVERVIEW OF THE '802 PATENT

The specification of U.S. Patent No. 8,163,802 ("the '802 Patent") describes the invention as "products and methods that involve the use of products heretofore developed for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages." (Ex. 1, '802 Patent, 1:63–67.) The electrostatic field reduces "the inflow of airborne contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body." (*Id.* at 1:67–2:2.) In other words, the formulation "capture[s] and hold[s] the contaminants including viruses, bacteria, and other harmful microorganisms or toxic particulates, inactivate[s] them dermally outside the body and render[s] them harmless." (*Id.* at 2:3–7.)

The '802 Patent also describes the various functions (or "Objects of the Invention") to be performed by the claimed compositions and methods:

- "capable of capturing particulates and microorganisms" (*Id.* at 2:66–67)

- "capability to hold it for a duration from being dislodged in to the air stream again" (*Id.* at 3:1–3)

- "will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition" (*Id.* at 3:7–9)

With respect to the above-listed "Objects of the Invention," the '802 Patent describes the purported novelty of the invention as follows:

> These and other objects of the invention are unexpected achieved by an electrostatically charged composition having at least one polymeric quaternary compound in an aqueous or non-aqueous based formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless.

(*Id.* at 3:32–40.)

Trutek has asserted claims 1, 2, 6 and 7 of the '802 Patent ("the Asserted Claims") in this litigation against BlueWillow:

> 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation where a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
> a) electrostatically attracting the particulate matter to the thin film;
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
> c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.
>
> 2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one

> cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
> a) electrostatically attracts the particulate matter to the thin film;
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
> c) inactivates the particulate matter and renders said particulate matter harmless.
>
> 6. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride.
>
> 7. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride or Lysine HCL.

III. ARGUMENT

A. Several Claim Terms Render All of the Asserted Claims Indefinite and Invalid

The claim terms "electrostatically inhibiting," "electrostatically attracting," "adequate impermeability," and "render[s] said particulate matter harmless" render each of the asserted claims of the '802 Patent invalid as indefinite under 35 U.S.C. § 112(a). ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention"). Each of these claim terms are found in independent claims 1 and 2, as well as dependent claims 6 and 7 (which depend from claim 2 and as such, necessarily incorporate the same claim elements).

As explained above, indefiniteness is a question of law that is proper for consideration by the Court during the claim construction process. "[A] patent is

invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 572 U.S. at 901. As set forth by the U.S. Supreme Court in *Nautilus*, indefiniteness is "evaluated from the perspective of someone skilled in the relevant art" and the claims should be "read in light of the patent's specification and prosecution history." *Id.* at 908. Thus, it is proper to consider expert opinion during the claim construction process when evaluating whether the asserted claims are indefinite.

For the reasons set forth below and in the supporting declaration of Dr. Mansoor Amiji, these four claim limitations contain relative, subjective and general terms, which when read in view of the specification and prosecution history, fail to inform a person of ordinary skill in the art ("POSA") of the scope of the claimed invention with reasonable certainty.[1] (Ex. 2, Amiji Decl. at ¶¶ 30–31.)

1. "electrostatically inhibiting" and "electrostatically attracting" (claims 1 & 2)

The preambles of claims 1 and 2 (which the parties agree are limiting) recite a method and formulation for "***electrostatically inhibiting*** harmful particulate matter from infecting an individual." Both claims also recite a method and

[1] The Parties' experts dispute the level of skill of a POSA. (Ex. 2, ¶¶ 26–28.) Thus, Dr. Amiji has also explained why a POSA according to Trutek's proposed lower standard for a POSA would have even more difficulty in ascertaining the scope of the claims with reasonable certainty. (*Id.* at ¶¶ 29, 39–40.)

formulation for "***electrostatically attracting*** [attracts] the particulate matter to the thin film." While the Detailed Description of the Invention refers generally to "electrostatically charged nasal application products" (Ex. 1, 3:44–52), the '802 Patent does not provide any information or guidance to a POSA to allow such person to assess with reasonable certainty the scope of potential formulations that are capable of achieving the claimed functions of "electrostatically inhibiting" and "electrostatically attracting" harmful particulate matter. (Ex. 2, ¶¶ 32–33 (emphasis added).)

More specifically, while the '802 Patent provides a laundry list of possible ingredients and formulations for making "electrostatically charged" nasal products, there are no examples, data or test results demonstrating that any of the formulations "electrostatically attract" harmful particulate matter to the thin film, as opposed to other negatively charged particles that are not harmful (such as dust). Nor are there any examples, data or test results demonstrating that the claimed formulations "electrostatically inhibit" the harmful particulate matter from infecting an individual. (*Id.* at ¶¶ 33–35.)

Nor does the '802 Patent provide any information concerning the objective parameters a POSA would need to assess to determine whether a formulation operates to "electrostatically attract" and "electrostatically inhibit" harmful particulate matter. For example, the '802 Patent is silent as to the specific charge

density or other quantitative parameters needed to create the electrostatic field, what magnitude of electrostatic field is necessary to attract oppositely charged contaminants, how far the electrostatic field needs to be from the application surface, how much of the product must be applied to be effective, or how long the composition must stay on the skin to be effective. (*Id.* at ¶ 36.) In other words, while the '802 Patent generally describes using "electrostatically charged" nasal products, the patent provides no guidance to the POSA on how to determine whether any such "electrostatically charged" nasal formulation falls within the boundaries of the claim in terms of its ability to "electrostatically attract" and "electrostatically inhibit" harmful particulate matter. (*Id.* at ¶¶ 32–36.)

Without any such objective guidance or criteria in the '802 Patent, the use of the subjective terms "electrostatically attracting" and "electrostatically inhibiting" in the asserted claims renders the claims indefinite as they do not allow a POSA to assess with reasonable certainty the scope of the claimed invention. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370–71 (Fed. Cir. 2014) ("[T]he claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art."); *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005) (stating that "[s]ome objective standard must be provided in order to allow the public to determine the scope of the claimed invention"). The lack of any such objective

guidance in the '802 Patent as to the meaning of these terms is also analogous to the use of the phrase "half-liquid" in *IBSA Institut Biochimique, S.A. v. Teva Pharm. USA, Inc.*, 966 F.3d 1374 (Fed. Cir. 2020). There, the Federal Circuit held the claim indefinite where the intrinsic record (claims, specification and prosecution history) failed "to establish the boundaries of a 'half-liquid'" and where the extrinsic record (expert testimony) established "the difficulty a POSA would face in ascertaining the boundaries of a 'half-liquid.'" *Id*. at 1378–81.

2. "adequate impermeability" (claims 1 & 2)

The use of the phrase "provide ***adequate impermeability*** to the thin film" in claims 1 and 2 also renders each of the asserted claims indefinite. The plain language of the phrase "adequate" is both subjective and a term of degree, and the intrinsic record provides no information to a POSA as to how impermeable the thin film must be, the purpose for the impermeability, what level of impermeability is required to be "adequate" with respect to the particular harmful particulate matter, or how to test the level of impermeability. (Ex. 2, ¶ 37.)

Without any objective guidance or criteria in the intrinsic record as to the level of impermeability required (or the purpose for the impermeability or how to test for it), a POSA has no way to determine whether any thin film formed upon application of the formulation to the skin has "adequate impermeability." *See Intellectual Ventures I LLC v. T-Mobile USA, Inc.*, 902 F.3d 1372, 1381 (Fed. Cir.

2018) (finding claim indefinite based on subjective term of degree "optimizing . . . QoS"). There, the Federal Circuit reasoned that "merely understanding that 'optimizing . . . QoS' related to the end-user experience fail(ed) to provide one of ordinary skill in the art with any way to determine whether QoS ha(d) been 'optimized.'" *Id.* Similarly, in *Dow Chemical Co. v. Nova Chemicals Corp.*, the term "slope of strain hardening coefficient" was held to be indefinite because the patent failed to teach with reasonable certainty where and how the "slope of strain hardening" should be measured. 803 F.3d 620, 633 (Fed. Cir. 2015). Likewise, in *Interval Licensing*, the Federal Circuit held the term "in an unobtrusive manner" to be a term of degree that was "highly subjective" on its face while providing "little guidance to one of skill in the art." *Interval Licensing*, 766 F.3d at 1371–73 (finding claims indefinite in further view of intrinsic record, which did not provide any objective definition or boundaries for the term).

The '802 Patent fails to teach what "adequate impermeability" means, why it is necessary, how to measure the level of impermeability, or what level of impermeability is required to provide "adequate impermeability," particularly in view of the wide range of harmful particulate matter and pathogens that the formulation is intended to address. (Ex. 2, ¶¶ 37–38.) As such, a POSA would not be able to assess with reasonable certainty whether any potential formulations fall within the subjective bounds of providing "adequate permeability" to the thin film.

3. "render[s] said particulate matter harmless" (claims 1 & 2)

Asserted claims 1 and 2 both conclude with the limitation of "render[s] said particulate matter harmless." The term "harmless" is a general concept that can be highly subjective depending on the context of the specific particulate matter that is to be rendered "harmless." Rather than providing clarity to the meaning of the term "render[s] said particulate matter harmless," the '802 Patent specification and prosecution history only add further uncertainty.

For example, the '802 Patent acknowledges that varying the percentages of the ingredients of the formulation can affect its potency and consistency, both of which would have an impact on the ability of the formulation to "render said particulate material harmless." (*Id.* at ¶¶ 32, 35.) Yet, the '802 Patent does not provide the POSA with any information or guidance as to how the percentages of the ingredients can be varied while still achieving "the same results." *Id.*

Moreover, the '802 Patent identifies an extremely broad range of particulate matter that the claimed invention is intended to render "harmless," including "various irritants and noxious substances," ('802 Patent at 1:59–60), "viruses, bacteria, and other harmful microorganisms or toxic particulates," (*id*. at 2:5–6), "oppositely charged airborne particulates (including microorganisms)," (*id*. at 3:36–37), "airborne contaminants," (*id*. at 3:46), "anthrax spores, human corona virus, smallpox virus, influenza virus, avian flu virus, swine flu virus, rhino virus,

and other biological or chemical elements/toxins/irritants, and the like," (*id*. at 3:56–59), as well as particulate matter that causes "allergies, asthma, and pathogenic infections of the respiratory tract," (*id*. at 3:62–63). As to how the formulation operates, the '802 Patent broadly explains that the claimed "electrostatically charged nasal application products" operates to "hold the contaminants . . . outside the body and render them harmless." (*Id*. at 3:49–52.)

The '802 Patent, however, does not provide any guidance to the POSA as to what amount or percentage of the particulate matter must be held in order to render it "harmless" to an individual. (Ex. 2, ¶ 38.) Nor does the '802 Patent identify any test or means to allow a POSA to determine how much particulate matter is held by a particular formulation and whether it is in fact rendered "harmless" to the individual. (*Id*.) This uncertainty is exacerbated by the wide range of particulate matter the claimed invention is intended to render "harmless." In this regard, the properties of individual pathogen particles vary greatly, and the '802 Patent does not provide any guidance to the POSA on what type of composition or dosage will be needed to render these pathogen particles harmless. (*Id*.)

For example, a formulation that holds only 50% of a relatively mild irritant may be sufficient to render it "harmless," whereas if that same formulation only held 50% of a highly toxic substance (e.g., anthrax spores), it likely would not be sufficient to render the toxic substance "harmless." This is analogous to claims

addressed by the Federal Circuit in *Saso Golf, Inc. v. Nike, Inc.*, where the claim terms "toe" and "heel" (referring to regions of a golf club head) were too general to allow a POSA to determine how they should be measured for purposes of assessing whether a particular golf club fell within the scope of the claim. 843 F. App'x. 291, 293–296 (Fed. Cir. 2021) (affirming indefiniteness). In particular, the Federal Circuit agreed that there was no standard definition for the "toe" and "heel" of a golf club head and the patent did not inform a POSA as to the boundaries that should be used to measure the "toe" and "heel." *Id*. at 295–96.

In addition, whether enough of the particulate matter is rendered "harmless" depends on the individual as well. For example, only a small amount of viral particulate matter may need to be held by the formulation in order to render it "harmless" to an individual that has been vaccinated against that virus. Likewise, whether a certain amount of allergen is "harmless" to a particular individual depends on the level of severity of the allergy and the tolerance level of the individual. This is analogous to claims found indefinite in *Interval Licensing*, where the term "unobtrusive manner" was found to depend on the preferences of each individual and the particular circumstances. *Interval Licensing*, 766 F.3d at 1371. Simply put, there is no objective standard provided in the '802 patent to determine whether a formulation "render[s] said particulate matter harmless." *Id.* at 1370–71 ("[T]he claims, when read in light of the specification and the

prosecution history, must provide objective boundaries for those of skill in the art."); *Datamize*, 417 F.3d at 1350 ("[s]ome objective standard must be provided in order to allow the public to determine the scope of the claimed invention").

The prosecution history of the '802 Patent adds even more uncertainty to the scope of the asserted claims. During prosecution, the Examiner directed the applicant to change the word "preventing" in the preamble to "inhibiting," reasoning that "preventing" would imply, in its broadest sense, that all harmful material is blocked from entering the individual's system (an assertion that the Examiner found lacking), whereas "inhibiting" suggests that even if some harmful material enters the system, infection may be inhibited. (Ex. 3, August 25, 2011 Office Action, 2–4.) Given the '802 Patent's reference to extremely harmful particulate matter such as that of anthrax and smallpox, it is unclear how the claimed invention can render such material "harmless" if some of the material is permitted to enter the individual's nostril.

In summary, whether a particular composition falls within the scope of the claims could very well depend on both the perspective of the individual as to whether something is rendered "harmless" and the nature of the "particulate matter" that is to be rendered "harmless." A composition that could simultaneously infringe and not infringe depending on such circumstances is the "epitome of indefiniteness." *See Geneva Pharms., Inc. v. GlaxoSmithKline PLC,*

349 F.3d 1373, 1384 (Fed. Cir. 2003) ("In other words, ***a given embodiment would simultaneously infringe and not infringe the claims***, depending on the particular bacteria chosen for analysis. . . . ***That is the epitome of indefiniteness***.") (emphasis added); *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1254–55 (Fed. Cir. 2008) ("When a proposed construction requires that an artisan make a separate infringement determination for every set of circumstances in which the composition may be used, and when such determinations are likely to result in differing outcomes (sometimes infringing and sometimes not), that construction is likely to be indefinite . . . .").

In summary, the wide range of particulate matter that can be rendered "harmless," coupled with the lack of any objective standard, guidelines or tests in the '802 Patent and the subjective nature of whether something is "harmless" to a particular individual, renders the asserted claims indefinite as they fail to inform a POSA as to the scope of the claimed invention with reasonable certainty.

B. The Preambles of Claims 1 and 2

Claim Term	Blue Willow's Construction	Trutek's Construction
"A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue	Preamble is limiting; plain and ordinary meaning, no further construction necessary	Claim 1 is a method claim, which recites preventing an individual from becoming infected from inhaling harmful airborne contaminant particles.

of nasal passages of the individual in a thin film, said method comprising" (claim 1)		A formulation, which exhibits a static electrical charge, is applied to the individual's nostrils, and it forms a statically charged thin film thereon.
"A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied" (claim 2)	Preamble is limiting; plain and ordinary meaning, no further construction necessary	A formulation, when applied to a person's nostrils, forms a thin film therein and prevents that person from becoming infected from inhaling harmful airborne contaminant particles. The formulation contains at least one cationic agent. A cationic agent produces a positive electrostatic charge. The formulation also contains a biocide.

The parties agree that the preambles of claims 1 and 2 (the only asserted independent claims) should be construed as limiting. However, the parties disagree as to whether further construction is necessary. Blue Willow believes that the preambles of claims 1 and 2 are sufficiently clear (apart from the issues of indefiniteness raised above) and that Trutek's constructions improperly seek to broaden the scope of the preambles beyond their plain and ordinary meaning.

First, other than the phrase "electrostatically inhibiting," which is indefinite for the reasons provided above, the remainder of the preamble language is facially clear such that no further construction is needed. The remainder of the preambles

recite commonly understood terms, and neither the specification nor prosecution history imparts any special meaning for these terms. Thus, any further construction of the preambles would be an "exercise in redundancy." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

Second, Trutek's proposed constructions for the preambles of claims 1 and 2 read out the requirement that the formulation exhibits or produces a charge that is sufficient to "electrostatically inhibit[] harmful particulate matter from infecting an individual through nasal inhalation." Instead, Trutek's proposed constructions merely require that the formulation "exhibits a static electrical charge" (claim 1) or "contains at least one cationic agent" that "produces a positive electrostatic charge" (claim 2). Thus, Trutek's proposed constructions read out the express claim requirement that the electrostatic charge be sufficient such that it is capable of trapping harmful particulates and inhibiting those harmful particulates from infecting the individual. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997) ("[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention"); *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("claims are interpreted with an eye toward giving effect to all terms in the claim").

Indeed, Trutek's proposed construction would undermine the stated purpose of the claimed invention. The Summary of the Invention states that:

> [t]hese and other objects of the invention are unexpectedly achieved by ***an electrostatically charged composition*** having at least one polymeric quaternary compound in an aqueous or non-aqueous based formulation, ***which when applied*** to a surface, creates ***an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped***, ***held thereto*** and one or more of the ***microorganisms so captured is neutralized, killed, inactivated, and rendered harmless***.

(Ex. 1, '802 Patent, 3:32–40 (emphasis added)). In other words, the purportedly inventive composition is not just any composition with an electrostatic charge, but rather, an electrostatic charge that is sufficient to create an electrostatic field that can trap oppositely charged airborne particulates, hold those particulates, and neutralize, kill, inactivate or render them harmless. Consistent with the stated purpose of the claimed invention, the '802 Patent specification expressly states the functionality to be achieved by the claimed compositions and methods, i.e., they must be "capable of capturing particulates and microorganisms," they must "hold [the particulate matter] for a duration from being dislodged in to the air stream again," and "will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition." (*Id.* at 2:66–67, 3:1–3, and 3:7–9.)

Accordingly, Trutek's proposed constructions are improper as they would remove the purportedly novel aspect of the patents from the preambles. *See Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007) ("[w]hen a patent . . . describes the features of the 'present invention' as a whole, this description limits the scope of the invention").

C. The Remaining Terms for Which Trutek Is Seeking Construction

Claim Term	Blue Willow's Construction[2]	Trutek's Construction
"a) electrostatically attracting the particulate matter to the thin film" (claim 1)	Plain and ordinary meaning, no construction necessary	The formulation's electrostatically charged thin film attracts oppositely charged harmful particles.
"b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and" (claim 1)	Plain and ordinary meaning, no construction necessary	The thin film formulation is designed to adhere to the skin or tissue of the nostrils and to be impermeable. The thin film captures and holds the harmful particles (that were attracted to it) in place.
"c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless" (claim 1)	Plain and ordinary meaning, no construction necessary	The formulation contains at least one ingredient that inactivates the captured harmful particles and renders them harmless.
"a) electrostatically attracts the particulate matter to the thin film" (claim 2)	Plain and ordinary meaning, no construction necessary	Oppositely statically charged harmful particles are attracted to the formulation's thin film.
"b) holds the particulate matter in place by	Plain and ordinary meaning, no construction	The thin film formulation is designed to adhere to

[2] For clarity, BlueWillow's statement that plain and ordinary meaning applies and no further construction is necessary applies to the remainder of the claim language, apart from the terms above that BlueWillow contends render the claims indefinite.

adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film" (claim 2)	necessary	the skin or tissue of the nostrils and to be impermeable. The thin film captures and holds the harmful particles (that were attracted to it) in place.
"c) inactivates the particulate matter and renders said particulate matter harmless" (claim 2)	Plain and ordinary meaning, no construction necessary	The biocide in the formulation inactivates the captured harmful particles and renders them harmless.
"the at least one cationic agent is Benzalkonium Chloride" (claim 6)	Plain and ordinary meaning, no construction necessary	The "at least one cationic agent" referred to in claim 2 is Benzalkonium Chloride, which is a known cationic agent.
"the at least one biocidic agent is Benzalkonium Chloride" (claim 7)	Plain and ordinary meaning, no construction necessary	The "at least one biocidic agent" referred to in claim 2 is Benzalkonium Chloride, which is a known biocidic agent.

Trutek appears to misunderstand the claim construction process. Instead of identifying specific terms where there is a dispute as to their meaning or a need for a more precise construction, Trutek essentially proposes to restate each limitation of the asserted claims. Except for the preambles discussed above, Trutek's "constructions" do nothing more than provide synonyms and/or restate the limitation using essentially the same language already present in the claims. This is contrary to the purpose of claim construction and wholly unnecessary.

While claim construction is an issue of law for the court, the Federal Circuit has made clear that the court is not required to "repeat or restate every claim term in order to comply with the ruling that claim construction is for the court." *U.S. Surgical*, 103 F.3d at 1568. Rather, the purpose of claim construction is "to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." *Id.* Moreover, claim construction "is not an obligatory exercise in redundancy." *Id.* Accordingly, claim construction is necessary only "when the meaning or scope of technical terms and words of art is unclear . . . and requires resolution in order to determine" the issue before the court. *Id.*; *see also Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy").

Another court from this circuit provided a useful example of the circumstances when a court should and should not construe particular claim terms. In *Static Control Components, Inc. v. Lexmark Int'l, Inc.*, the court addressed the issue of whether it was obligated to construe each term raised for construction by either party. 502 F. Supp.2d 568, 575 (E.D. Ky. 2007). In concluding that no such obligation existed, the court explained:

> A simple illustration should demonstrate the lack of real conflict in the current case: assume a claim limitation is the term "dog." One party argues that, based on intrinsic evidence, a "dog" must be construed as "weighing less than 50 lbs." Accordingly, that party

> argues that its accused dog is non-infringing because the accused dog weighs 30 lbs. This would be an exercise in construction. However, arguing that "dog" ought to be construed as "canine" is no construction at all. ***The terms are mere synonyms that leaves the Court to wonder what the point is.*** Under what circumstance would an accused dog infringe but an accused canine would not? Ultimately, there is no dispute in the first instance regarding the claimed term.

Id. (emphasis added). Trutek's proposed constructions suffer from the same problem, i.e., they are akin to proposing no construction at all.

For example, Trutek's construction of "a) electrostatically attracting the particulate matter to the thin film" to mean "[t]he formulation's electrostatically charged thin film attracts oppositely charged harmful particles," is nothing more than an "exercise in redundancy." *U.S. Surgical*, 103 F.3d at 1568. It is not all clear how this construction is in any way helpful in clarifying or explaining what is meant by the claim language. Thus, Trutek's proposed construction is nothing more than an "exercise in redundancy." *Id.*; *Graco Children's Prods., Inc. v. Chicco USA, Inc.*, 548 F. Supp. 2d 195, 204 (E.D. Pa. 2008) (refusing to construe term where plaintiff fail to explain that the construction was "necessary and would be more helpful to a juror than the plain language of the term itself").

Similarly, Trutek's proposed construction for "c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless" is also not helpful in clarifying the claim language as it essentially restates the claim element using the same language ("The formulation contains at

least one ingredient that inactivates the captured harmful particles and renders them harmless"). Trutek's proposed constructions for "the at least one cationic agent is Benzalkonium Chloride" and "the at least one biocidic agent is Benzalkonium Chloride" are particularly pointless. Trutek proposes construing these terms, respectively, as: "[t]he 'at least one cationic agent' referred to in claim 2 is Benzalkonium Chloride, which is a known cationic agent" and "[t]he 'at least one biocidic agent' referred to in claim 2 is Benzalkonium Chloride, which is a known biocidic agent." Thus, Trutek's constructions do nothing more than restate already clear claim language.

There is no reason for the court to adopt Trutek's proposed constructions for any of these terms. Because Trutek has not identified or proposed any special meaning for these claim terms, their plain and ordinary meaning should apply (to the extent the claim terms noted above are not found to be indefinite). *See Graco Children's Products*, 548 F. Supp.2d at 204.

IV. CONCLUSION

For the reasons set forth above, the Court should find each of the asserted claims 1, 2, 6 and 7 invalid as indefinite under 35 U.S.C. § 112, ¶ 2. In the alternative, if the claim terms are found to be sufficiently definite, the Court should construe the claim preambles as limiting and order that the all of the claim terms be given their plain and ordinary meaning.

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Respectfully submitted,

/s/ *Alan J. Gocha*

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CERTIFICATE OF SERVICE

I hereby certify that on September 8, 2022, I electronically filed the foregoing document and accompanying exhibits with the Clerk of the Court for the Eastern District of Michigan using the ECF System, which will send electronic notice to all participants.

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